Gregg L. Weiner
Stephen S. Rabinowitz
Fried, Frank, Harris, Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004-1980
(212) 859-8000
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,	:	ECF CASE
Plaintiff,	:	
- against -	:	07 Civ. 10376 (CSH)
PANION & BF BIOTECH, INC.,	:	**FIRST AMENDED COMPLAINT**
Defendant.	:	

Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx"), by its attorneys, for its First Amended Complaint in this action, alleges as follows:

NATURE OF ACTION

1. This is an action for declaratory and injunctive relief and damages arising from the threatened termination of a license agreement under which defendant Panion & BF Biotech, Inc. ("Panion") granted Keryx exclusive rights to develop and commercialize a licensed pharmaceutical product for treatment of kidney disease. Panion's asserted basis for terminating the license agreement is incorrect. Moreover, in conjunction with its improper termination threats, Panion breached the license agreement by failing to prosecute Japanese patent applications for the product in good faith and has tortiously interfered with Keryx's ongoing contractual relations with third parties who are assisting Keryx in developing the licensed product.

Panion's actions have damaged Keryx and will further threaten Keryx with irreparable harm for which it has no adequate remedy at law.

PARTIES AND JURISDICTION

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with its principal place of business at 750 Lexington Ave., 20th Floor, New York, NY 10022.

3. Upon information and belief, Panion is a corporation organized and existing under the laws of Taiwan, having its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan. In papers it has filed in New York State Supreme Court, Panion states that it has an office in Queens County, New York.

4. This action arises under the common law of the State of New York and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 et seq.

5. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(a). The parties are of diverse citizenship, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars ($75,000), exclusive of interest and costs.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

BACKGROUND

7. Keryx is a pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious and life-threatening diseases, including diabetes, cancer, and renal (kidney) disease.

The License Agreement

8. Panion is the owner or exclusive licensee of certain patents and patent applications, including U.S. Patent No. 5,7753,706, issued May 19, 1998, for an invention entitled "Methods For Treating Renal Failure" (the "Hsu Patent"). The Hsu Patent describes and claims a method of controlling phosphate retention and hyperphosphatemia (elevated phosphate levels) in patients suffering from advanced kidney disease by administering a therapeutically effective amount of ferric citrate. Phosphate retention leading to elevated phosphate levels is a common and serious complication of advanced kidney disease.

9. Keryx and Panion are parties to a license agreement, dated November 7, 2005 (the "License Agreement") whereby Panion (as Licensor) granted to Keryx (as Licensee) an exclusive license, throughout a designated Territory, under the Hsu Patent, its corresponding foreign counterparts, and other Panion-owned or Panion-controlled patents and patent applications, to develop and commercialize ferric citrate and pharmaceutical products containing ferric citrate as an active ingredient (collectively, the "Product") for treatment of kidney disease. The designated Territory covers most of the world and includes the United States, Canada and Japan.

10. Section 3.1 of the License Agreement provides:

> Grant. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive license, in the Territory, with the right to sublicense, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export the Product in the Territory under the Licensor Know-How, and the Patent Rights for all Indications in the Field.

11. As defined in Section 1.13 of the License Agreement, the term "Licensor Know-How" includes:

> discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, which as of the Effective Date and during the term of this Agreement are necessary or useful to Licensee in connection with the development, registration, manufacture, marketing, use or sale of a Product.

12. Section 7.7 of the Agreement provides, in part:

> (a) Both parties agree to work in good faith to fully collaborate to review and administer the manufacturing program for the Compound and to resolve any technical issues both immediately after the Effective Date and at least annually thereafter during the Exclusive Supply Period as defined below.
>
> (b) For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

13. After entering into the License Agreement, Keryx and Panion began discussing the development of updated specifications for ferric citrate, based on regulatory guidance, and improved processes for manufacturing pharmaceutical-grade ferric citrate at commercially reasonable cost. A supply of pharmaceutical-grade ferric citrate is indispensable for performing the critical toxicology testing and clinical trials that are needed to obtain regulatory approval from the Federal Food and Drug Administration ("FDA") and its foreign counterparts to commercialize pharmaceutical agents containing ferric citrate as an Active Pharmaceutical Ingredient ("API").

Panion's Acquiescence in Keryx's Orders of API

14. As set forth below, Panion did not object to Keryx's sourcing of ferric citrate from BioVectra even though Panion was well aware of that production both before it occurred and immediately afterwards. On July 26, 2006, Keryx sent an email to Panion advising that Keryx urgently needed 100kg of ferric citrate (API) for use in critical toxicology studies. In response, Panion introduced Keryx to Panion's previous contractor, BRI Biopharmaceutical Research Inc. ("BRI"), located in Vancouver, Canada, for the purposes of organizing supply but declined to be involved in the planning, saying that it just wanted to be kept informed. Keryx kept Panion informed of its development program and invited Panion to attend meetings with BRI, which Panion declined on the grounds that "Panion is a small company with limited budget and resources."

15. On August 28, 2006, Keryx again emailed Panion, this time requesting ferric citrate even in quantities as low as 5 kg. On September 1, 2006, Panion

responded that it had "checked the inventory and found out we don't have any quantity in stock." Panion's responses to the emails of July 26, 2006 and August 28, 2006 did not include any offer to manufacture or procure ferric citrate for Keryx's use.

16. BRI introduced Keryx to BioVectra DCL ("BioVectra"), located in Prince Edward Island, Canada, and through BioVectra to a subcontractor, the PharmPro Services division of Fluid Air, Inc. ("PharmPro"), located in Aurora, IL among other places. On September 5, 2006, Keryx placed a purchase order with BioVectra for the manufacture of 400 kg of ferric citrate (API) in 3 lots, under a quotation that Panion had requested BRI to obtain and that BRI had emailed to Keryx, with a copy to Panion, on August 24, 2006.

17. On September 11, 2006, Keryx emailed Panion referring to the "large prep[aration] of Fe[rric] Citrate" that Keryx was about to have manufactured and offering to increase that order to accommodate "any API needs" that Panion might have. Without objecting to Keryx's order or offering to take over the work of coordinating the production, Panion responded that it had sufficient API for its own purposes. After receiving Panion's response, Keryx ordered a fourth lot of ferric citrate (API) from BioVectra. After ordering the fourth lot of ferric citrate, but before production began, Keryx again emailed Panion, between October 17 and October 25, 2006, referring to Keryx's "forthcoming production at BioVectra." Despite its awareness of the impending production of ferric citrate at BioVectra for Keryx, Panion did not notify Keryx that it had any objection. Nor did Panion offer to participate in any active way. Production of the four lots of ferric citrate for Keryx

commenced at BioVectra on October 27, 2006 and was completed in December, 2006.

18. Working with BRI, BioVectra and PharmPro, Keryx has incurred significant expenditures and devoted substantial corporate resources to the development of specifications and manufacturing processes for API. Panion was copied on emails concerning discussions of changes in specifications and controls. On December 4, 2006, Panion approved, in draft, new ferric citrate specifications proposed by Keryx, with minor amendments. On January 10, 2007, Keryx emailed to Panion a revised draft of the new ferric citrate specifications, requesting Panion's prompt approval of those specifications in order to meet Keryx's deadline for release of the newly-manufactured ferric citrate (API). On January 12, 2007, Panion responded to the January 10, 2007 email without objecting to the fact that BioVectra had manufactured ferric citrate (API) for Keryx. On or about February 17, 2007, Panion formally approved the new specifications for ferric citrate (API). On March 1, 2007, Keryx submitted those new ferric citrate specifications to the FDA. In April, 2007 the four lots of ferric citrate (API) were determined to be in compliance with the specifications that Panion had approved in February, and were formally released, with title passing to Keryx. On July 30, 2007, Panion wrote to Keryx acknowledging its awareness that "Keryx, with the Panion subcontractor BRI help, has manufactured a new batch of drug substance" and asking Keryx to provide "the final executed batch records and final specifications for the newly manufactured batch so that we can file the updated information to update the D[rug] M[aster] F[ile] . . . ." Even though Panion had known since January, 2007 that BioVectra had produced ferric citrate

(API) for Keryx, Panion did not object to that production in its email of July 30, 2007 or in any earlier communication with Keryx. On September 11, 2007, Keryx provided the batch records for the four lots of ferric citrate that BioVectra had produced for Keryx, including Certificates of Analysis demonstrating that those four lots were in compliance with the specifications that Panion had approved in February, 2007. On September 17, 2007, Panion acknowledged receipt of those batch records

19. Keryx has contracted and borne the entire expense for additional development work by BRI, BioVectra and PharmPro aimed at improving the efficiency (i.e., lowering the cost and increasing the yield) of producing ferric citrate (API) and assuring its stability. This development work, which is still continuing, does not result in Keryx being supplied with additional ferric citrate (API) over and above the four lots that Keryx previously ordered. Keryx has now made a substantial investment in lowering the cost of manufacturing which is a critical component of commercializing ferric citrate (i.e., the development of a commercially feasible, cost-effective process for manufacturing pharmaceutically pure ferric citrate (API) suitable for clinical trials and commercial sale).

The Japanese Sublicense and Panion's Subsequent Misconduct

20. On September 26, 2007 Keryx concluded an agreement (the "Sublicense") with Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd. (collectively,"Japan Tobacco") by which Keryx granted to Japan Tobacco an exclusive sublicense under the License Agreement to develop and commercialize ferric citrate in Japan, in exchange for an initial payment of $12 million plus future milestone and royalty payments. Although the License Agreement does not give

Panion any right to share in the initial payment by Japan Tobacco, Panion nevertheless has repeatedly sought to share in that initial payment.

Panion's Threatened Termination and Interference With Licensed Activities

21. On October 31, 2007 Panion's counsel sent Keryx an email contending that Keryx's purchases of API, under contracts entered into a year earlier, constituted a "material breach" of the Licensing Agreement that "has not been cured for more than ninety days" and threatening to take "appropriate actions to nullify the agreement." The License Agreement gives Panion (Licensor) a right to terminate for cause "upon or after the breach of any material provision . . . by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof . . . ." No prior written notice of any alleged breach of the Licensing Agreement had been given to Keryx before October 31, 2007.

22. On or about November 8 and 9, 2007, Panion accused BRI, BioVectra and PharmPro of making improper use of Panion-owned technology and threatened to commence legal action against them unless they discontinued their contractual activities for Keryx.

23. On November 12, 2007, Keryx's counsel wrote to Panion's counsel pointing out that Panion had acquiesced in Keryx's prior purchases of API, stating that Keryx had no pending unfilled orders for supply of API, agreeing that Keryx would submit future purchase orders for supply of API to Panion in accordance with Section 7.7 of the License Agreement, and demanding that Panion cease and desist from threatening Keryx's contractors and that Panion retract the demands and allegations it had issued to them. Panion failed to respond to Keryx's overtures.

24. Instead, on November 13, 14 and 15, 2007, Panion's counsel again contacted PharmPro, BRI and BioVectra, respectively, again threatening that Panion would commence legal action unless they discontinued their contractual activities for Keryx.

25. On November 15, 2007, Panion filed a Summons with Notice in New York State Supreme Court, County of Queens, asserting claims against BRI and seeking injunctive relief to stop BRI's activities on behalf of Keryx. On November 19, 2007, Panion filed a Summons with Notice in New York State Supreme Court, County of Queens, asserting claims against BioVectra and seeking injunctive relief to stop BioVectra's activities on behalf of Keryx.

FIRST CAUSE OF ACTION
(Breach of contract)

26. Paragraphs 1-25, above, are realleged and incorporated by reference as if set forth in full.

27. Under the License Agreement, Panion has authorized Keryx to use Panion-owned technology to "develop [and] have developed" ferric citrate and pharmaceutical compositions containing ferric citrate as an active pharmaceutical ingredient (the licensed Product).

28. The threats and demands issued by Panion against BRI, BioVectra and PharmPro constitute a breach of Keryx's rights under the License Agreement to develop the licensed Product.

29. Panion's conduct has damaged Keryx and further threatens Keryx with irreparable harm for which it has no adequate remedy at law.

SECOND CAUSE OF ACTION
(Tortious interference with contractual relations)

30. Paragraphs 1-29, above, are realleged and incorporated by reference as if set forth in full.

31. By demanding that BRI, BioVectra and PharmPro cease the development activities they are performing for Keryx, Panion has tortiously interfered with the ongoing contractual relationships between Keryx and BRI, BioVectra and PharmPro. Panion has made these demands knowing that they are contrary to the rights granted Keryx under the License Agreement and for the purpose of harming Keryx.

32. Unless enjoined, Panion will continue to interfere with Keryx's contractual relationships with BRI, BioVectra and PharmPro.

33. Panion's conduct has damaged Keryx and further threatens Keryx with irreparable harm for which it has no adequate remedy at law.

THIRD CAUSE OF ACTION
(Declaratory judgment that Keryx has not breached the License Agreement)

34. Paragraphs 1-33, above, are realleged and incorporated by reference as if set forth in full.

35. Keryx's direct order for supply of four lots of ferric citrate (API) manufactured by BioVectra in conjunction with BRI and PharmPro did not breach the License Agreement. Panion acquiesced in and consented to those purchases.

36. Alternatively, Panion is estopped from contending that Keryx's direct order for supply of four lots of ferric citrate (API) manufactured by BioVectra in conjunction with BRI and PharmPro constitutes a breach of the License Agreement.

37. Moreover, any alleged breach by virtue of Keryx's direct order for supply of four lots of ferric citrate (API) manufactured by BioVectra in conjunction with BRI and PharmPro was not a material breach of the License Agreement.

38. A ripe, justiciable controversy exists between Panion and Keryx concerning whether Keryx has breached the Agreement by purchasing four lots of ferric citrate (API) manufactured by BioVectra in conjunction with BRI and PharmPro.

FOURTH CAUSE OF ACTION
(Anticipatory breach)

39. Paragraphs 1-38, above, are realleged and incorporated by reference as if set forth in full.

40. Section 12.3.1. of the License Agreement prohibits Panion from terminating the License Agreement for a material breach unless and until Keryx has failed to cure the breach within ninety (90) days after Panion has given Keryx written notice thereof.

41. In its initial notice dated October 31, 2007, Panion stated that Keryx's alleged material breach "has not been cured for more than ninety days" and threatened to take "actions to nullify th[e] agreement." Panion thereby breached the termination clause of the License Agreement by failing to give Keryx ninety days after notice to cure the alleged breach. Moreover, Panion has refused to rescind its threat to terminate the License Agreement without giving Keryx the benefit of the ninety-day cure period provided in the License Agreement.

42. Panion is not entitled to terminate the License Agreement prior to expiration of the cure period and its threat to do so breaches the express provisions thereof.

43. Panion's conduct has damaged Keryx and threatens Keryx with irreparable harm for which it has no adequate remedy at law.

FIFTH CAUSE OF ACTION
(Breach of contract)

44. Paragraphs 1-43, above, are realleged and incorporated by reference as if set forth in full.

45. Section 8.1.1 of the License Agreement provides:

> Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights . . . using outside patent counsel acceptable to Licensor. Licensor shall be solely responsible for all costs and expense relating to such patent applications and patents. Licensor shall regularly consult with Licensee and shall keep Licensee advised of the status of all patent applications and patents relating to the Patent Rights by providing Licensee with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Licensor and responses or other papers filed by Licensor. Licensor specifically agrees to provide Licensee with copies of patent office correspondence in sufficient time for Licensee to review and comment on such correspondence and submit to Licensor any proposed response thereto. Licensor further agrees to provide Licensee with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents.

46. Keryx has repeatedly requested Panion to provide a comprehensive docket report on the Patent Rights licensed to Keryx under the License Agreement.

Panion has neither provided the requested comprehensive docket report, nor provided any explanation for its failure to comply with these requests.

47. On or about August 28, 2007, the Japanese Patent Office issued a second Office Action ("the pending Office Action") concerning Japanese Patent Application No. 10-527705, a foreign counterpart of the Hsu Patent. Despite Keryx's repeated requests for an updated patent docket report, Panion failed to notify Keryx of the pending Office Action until October 1, 2007. Docket reports sent by Panion to Keryx on September 5 and September 21, 2007 were incorrect and misleading because they did not reflect the pending Office Action. Panion provided Keryx with a patent docket report identifying the pending Office Action only after Keryx had agreed to pay the fees of Panion's patent counsel.

48. Panion initially permitted its Japanese patent counsel to collaborate with the patent counsel of Japan Tobacco, Keryx's sublicensee, in evaluating the pending Office Action and determining how to prepare a response. On information and belief, it was agreed at a meeting between Panion's Japanese patent counsel and Japan Tobacco's patent counsel that a 3-month extension should be sought so that Japan Tobacco could undertake a comprehensive search to identify and analyze published articles that support allowance of the application as a patent. In accordance with its procedures and practice, the Japanese Patent Office would grant a request submitted on or before November 28, 2007 for a three-month extension of the deadline for responding to the pending Office Action.

49. On October 24, 2007, Panion's counsel notified Keryx that Panion would request a 3-month extension for responding to the pending Office Action. The

very next day, October 25, 2007, Panion's counsel sent Keryx a further email in which Panion withdrew its agreement to seek the extension "based on the unresolved issues between Keryx and Panion." Panion also instructed its Japanese patent counsel to stop interacting with the patent counsel of Japan Tobacco.

50. Keryx advised Panion that Japan Tobacco's searches had identified thousands of potentially relevant references, a number too large to evaluate in time to respond on November 28, 2007. Keryx repeatedly requested Panion to request a three month extension so that Japan Tobacco could complete its analysis, but Panion rejected Keryx's requests and refused to seek any extension.

51. Under pressure of time, Japan Tobacco was able to provide six relevant references identified thus far in its searches, which Keryx promptly forwarded to Panion's patent counsel. Panion informed Keryx that it had selected certain of those six references for inclusion in the response it would submit to the Japanese Patent Office, but refused to identify to Keryx which of the six references it had selected for that purpose. When Keryx asked to see how Panion's written submission had been revised to take account of the selected references, Panion responded that it would not amend its written submission to point out to the Japanese Patent Office why the selected references were relevant or how they supported allowance of the application as a patent.

52. Panion has breached the License Agreement by failing to use reasonable efforts to prosecute the licensed patent applications, by failing to keep Keryx informed of the status of the licensed patents and patent applications, by failing to consult in good faith with Keryx concerning prosecution of the licensed

patent applications, and by refusing to seek an extension of the November 28, 2007 deadline for responding to the pending Office Action.

53. Panion's conduct has damaged Keryx and threatens Keryx with irreparable harm for which it has no adequate remedy at law.

SIXTH CAUSE OF ACTION
(Breach of implied covenant of good faith and fair dealing)

54. Paragraphs 1-53, above, are realleged and incorporated by reference as if set forth in full.

55. The License Agreement contains an implied covenant of good faith and fair dealing.

56. Panion breached the implied covenant of good faith and fair dealing by instructing its Japanese patent attorneys to cease communicating with Keryx's Japanese sublicensees.

57. Panion breached the implied covenant of good faith and fair dealing by refusing to seek an extension of the November 28, 2007 deadline for responding to the pending Office Action in retaliation for unresolved contractual disputes between Panion and Keryx.

58. Panion also breached the implied covenant of good faith and fair dealing by, among other things, refusing to identify to Keryx which additional references Panion had selected for inclusion in its response to the pending Office Action, refusing to amend the written portion of Panion's response to address the selected references, and refusing to give Keryx 10 days to "review, comment and consult on" Panion's proposed response as amended by the inclusion of the selected references.

59. Panion's conduct has damaged Keryx and threatens Keryx with irreparable harm for which it has no adequate remedy at law.

WHEREFORE, Keryx demands judgment as follows:

1. Declaring that:

   a) Keryx is not in breach of the License Agreement;

   b) the alleged breach concerning orders for supply of ferric citrate is not material;

   c) Keryx has until at least January 30, 2008 to cure any alleged breach concerning orders for supply of ferric citrate; and

   d) any notice issued by Panion before January 30, 2008 purporting to terminate the License Agreement is null and void;

2. Preliminarily and permanently enjoining Panion:

   a) to consult in good faith with Keryx concerning prosecution of the licensed patent applications, including by (i) instructing Panion's Japanese patent counsel to communicate directly with the patent counsel of Japan Tobacco concerning prosecution of the licensed patent applications in Japan; and (ii) instructing Panion's Japanese counsel to request a three-month extension of the November 28, 2007 deadline for responding to the

pending Office Action in Japanese Patent Application No. 10-527705;

b) from refusing to make reasonable efforts to prosecute the licensed patent applications and refusing to consult in good faith with Keryx concerning prosecution of the licensed patent applications;

c) from taking any action to interfere with Keryx's rights under the License Agreement, including its right to use the services of third parties in order to develop the licensed Product ;

d) from tortiously interfering with Keryx's contractual relations with BRI, BioVectra, PharmPro and other contractors;

e) from commencing any new litigations against BRI, BioVectra, PharmPro or Keryx's other contractors arising from or relating to work done on behalf of Keryx; and

f) from issuing a notice to terminate the License Agreement before the expiration of Keryx's time to cure the alleged breach on account of which the License Agreement is terminated;

3. Directing Panion to pay Keryx's damages in an amount to be determined at trial and anticipated to exceed $1 million, with interest thereon;

4. Awarding Keryx punitive damages on its claim for tortious interference;

5. Awarding Keryx its costs and disbursements (including expert and attorneys' fees incurred in this action); and

6. Awarding Keryx such other and further relief as the Court may deem just and proper.

Dated: New York, New York
December 3, 2007

FRIED, FRANK, HARRIS, SHRIVER &
JACOBSON LLP

By: /s/
Gregg L. Weiner
Stephen S. Rabinowitz
(Members of the Firm)

One New York Plaza
New York, NY 10004-1980
(212) 859-8000

Attorneys for Plaintiff
Keryx Biopharmaceuticals, Inc.